Complete Summary

GUIDELINE TITLE

Peptic ulcer disease.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Peptic ulcer disease. Ann Arbor (MI): University of Michigan Health System; 2005 May. 9 p. [7 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. UMHS peptic ulcer guideline. Ann Arbor (MI): University of Michigan Health System; 1999 May. 6 p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Peptic ulcer disease (PUD)
- Helicobacter pylori (HP) infection

GUIDELINE CATEGORY

Diagnosis
Management
Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To implement a cost effective strategy incorporating testing for and eradication of Helicobacter pylori in patients with suspected peptic ulcer disease
- To reduce ulcer recurrence and prevent the overuse of chronic anti-secretory medications in peptic ulcer disease patients

TARGET POPULATION

Adults less than 50 years of age with peptic ulcer disease

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis of H. pylori (HP) infection

1. Non-invasive HP tests, such as antibody testing and tests for active HP (fecal HP antigen testing; urea breath testing)
2. Diagnostic endoscopy

Treatment

1. Proton pump inhibitor (PPI) based triple therapies:
    - PPI (lansoprazole or omeprazole), amoxicillin, and clarithromycin
    - The three packaged together: Prevpac® (using the PPI lansoprazole)
    - PPI (lansoprazole or omeprazole), metronidazole, and clarithromycin or amoxicillin
2. "Conventional Triple Therapy" for H. pylori:
    - Bismuth (Pepto-Bismol), metronidazole, and tetracycline or amoxicillin, combined with an H2 blocker (cimetidine, famotidine, nizatidine or ranitidine) or a PPI (lansoprazole or omeprazole)
    - The three packaged together: Helidac® combined with an H2 blocker (cimetidine, famotidine, nizatidine or ranitidine) or a PPI (lansoprazole or omeprazole)

    Note: Dual therapy of single PPI and a single antibiotic is not recommended.

Referral for further evaluation (gastroenterology)

MAJOR OUTCOMES CONSIDERED

- Symptomatic relief
- Relative effectiveness of anti-H. pylori (HP) therapies on eradication and recurrence rates for peptic ulcer disease (PUD)
- Assessment of diagnostic tests (sensitivity, specificity, predictive value, accuracy)
- Cost-effectiveness of diagnostic and treatment approaches to PUD

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature search began with results of literature searches performed for the period 1986 through September 1998 for earlier versions of this guideline. The literature search for this update was conducted prospectively using the major keywords of: peptic ulcer and H. pylori, dyspepsia and H. pylori, guidelines, controlled trials, adults, published from July 1998 through July 2004 on Medline. Terms used for specific treatment topic searches within the major key words included: history, serologic testing, endoscopy, other references to diagnosis, antibiotics, antisecretory drugs, other references to treatment, and other references not included in the previous specific topics. The search was conducted in components each keyed to a specific causal link in a formal problem structure (available upon request). The search was supplemented with very recent clinical trials known to expert members of the panel. Negative trials were specifically sought. The search was a single cycle.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of evidence for the most significant recommendations:

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trials (RCTs), if available, to the exclusion of other data; if RCTs were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Consideration of benefits, harms, costs, and patient preferences

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Published cost-effectiveness studies were reviewed. One study was an economic analysis that supported the role for initial noninvasive diagnosis and treatment of Helicobacter pylori infection (HP) in patients with suspected ulcer disease.

A large study was reviewed that demonstrated the effect and cost savings of initial serology-based treatment of HP in patients with suspected ulcer disease.

For more details, refer to the Annotated References section of the original guideline document.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

University of Michigan Health System (UMHS) guidelines are reviewed by leadership and in clinical conferences of in departments to which the content is most relevant. This guideline concerning peptic ulcer disease was reviewed by members of the following departments: Gastroenterology; General Medicine; Family Medicine.

Guidelines are approved by the Executive Committee of Clinical Affairs (ECCA).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on dosing and cost considerations for therapy for Helicobacter pylori (H. pylori [HP]) associated peptic ulcer disease (PUD).

The levels of evidence [A-D] are defined at the end of the "Major Recommendations" field.

- Clinical approach.

  Ulcers are caused by an infection of a bacterium known as Helicobacter pylori (HP) or H. pylori. Eradication of HP infection alters the natural history of peptic ulcer disease. Successful eradication reduces PUD recurrence rate from 90% to <5% per year [A]. PUD generally does not recur in the successfully treated patient unless nonsteroidal anti-inflammatory drug (NSAID) use is present.

- Diagnosis.

  Economic analyses demonstrate a cost effectiveness advantage of non-invasive testing and antibiotic therapy for HP in patients with symptoms suggestive of PUD when compared to immediate endoscopy. [C] Testing for active HP infection (stool antigen or urea breath testing) is more appropriate than serology testing in areas with low prevalence of active HP infection to reduce unnecessary treatment of individuals without active HP infection.

- Treatment.

  HP eradication therapy consists of antibiotics and anti-secretory drugs. [A] Long-term acid inhibition is inappropriate in the management of HP-related PUD in most instances. [B]

- Follow-up.

  Referral to the gastroenterologist should occur for all patients with signs and symptoms of complicated ulcer disease and for patients who fail initial therapy based on a non-invasive HP test. Persistent symptoms after 2 weeks of therapy suggest an alternative diagnosis.

Definitions:

Levels of evidence for the most significant recommendations:

A. Randomized controlled trials
B. Controlled trials, no randomization

C. Decision analysis
D. Opinion of expert panel

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for the management of peptic ulcer disease.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and graded for the most significant recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Cost-effective approach to diagnosis: Serologic testing for Helicobacter pylori (HP) is very accurate and the least expensive method for office diagnosis of infection in untreated patients.
- Economic analyses demonstrate a cost effectiveness advantage of non-invasive testing and antibiotic therapy for HP in patients with symptoms suggestive of peptic ulcer disease (PUD) when compared to immediate endoscopy.
- Effective treatment: Successful eradication of HP infection reduces PUD recurrence rate from 90% to less than 5% per year.

Subgroups Most Likely to Benefit

Testing for active infection (fecal Helicobacter pylori (HP) antigen testing; urea breath testing) may be more cost-effective in populations likely to have been previously treated successfully.

POTENTIAL HARMS

- The clinical approach involving initial serologic testing for Helicobacter pylori (HP) and antibiotic therapy for those patients who test positive for HP infection is associated with the risk of overtreating those patients who are infected with HP (or those with a false positive serology) but do not have active ulcer disease.
- Antibody tests do not differentiate between previously eradicated HP and currently active HP.
- Side effects of medications used in treatment of HP infection.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgement regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 Oct (revised 2005 May)

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

The University of Michigan Health System (UMHS) provides funding for guideline development. No external funds are used.

GUIDELINE COMMITTEE

Peptic Ulcer Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

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Speaker's bureau, AstraZeneca, TAP, Wyeth, Boheringer Ingelheim

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the University of Michigan Health System Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Peptic ulcer disease (PUD). University of Michigan Health System; 2005 Apr. Various p.

Electronic copies: Available from the University of Michigan Health System Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on August 21, 2000. The information was verified by the guideline developer on November 22, 2000. This summary was updated by ECRI on August 4, 2005. The updated information was verified by the guideline developer on August 10, 2005.

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